



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Strand et al. **Group Art Unit:** 1743
Serial No.: 10/033,315 **Examiner:** Alexander, Lyle
Filed: December 27, 2001 **Confirmation No.:** 1059
Title: Microfluidic Substrate Assembly and Method For Making Same

Mail Stop Appeal Brief-Patent
Commissioner For Patents
P.O. Box 1450
Alexandria, VA 22313-1450

APPEAL BRIEF

Sir:

This is an Appeal Brief in accordance with 37 C.F.R. § 41.37 in support of Appellant's December 16, 2004 Notice of Appeal.

Appeal is taken from the final Office Action mailed August 16, 2004. Please charge any necessary fees in connection with this Appeal Brief to our Deposit Account No. 19-0733.

Each section heading below starts on a new page.

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REAL PARTY IN INTEREST

37 C.F.R. § 41.37(c)(1)(i)

The owner of this application, and the real party in interest, is Protasis Corporation.

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RELATED APPEALS AND INTERFERENCES

37 C.F.R. § 41.37(c)(1)(ii)

There are no related appeals or interferences.

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STATUS OF THE CLAIMS

37 C.F.R. § 41.37(c)(1)(iii)

Claims 1-35 are pending in the application. No claims are allowed. No claims are objected to. All claims are rejected under 35 U.S.C. § 102 and/or § 103.

Claims 1-6, 8-19 and 27-35 are rejected to under 35 U.S.C. 102(b) as being anticipated by WO 99/60397 or Wilding et al (US 5,928,880).

Claims 1-6 and 8-12 are rejected under 35 U.S.C. 102(e) as being anticipated by Dubrow et al. (US 6,475,364).

Claims 1-6 and 8-14 are rejected under 35 U.S.C. 102(b) as being anticipated by Wilding et al. (seemingly US 5,928,880).

Claim 7 is rejected under 35 U.S.C. 103(a) over WO 99/60397 or Wilding et al. or Dubrow et al. in view of Mastrangelo et al. (US 6,494,433).

Claims 20-26 are rejected under 35 U.S.C. 103(a) over WO 99/60397 or Wilding et al. or Dubrow et al.

Claims 15-19 are rejected under 35 U.S.C. 103(a) over Wilding et al.

Claims 27-35 are rejected under 35 U.S.C. 103(a) over Wilding et al.

Appellant hereby appeals the rejection of claims 1-35.

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STATUS OF AMENDMENTS

37 C.F.R. § 41.37(c)(1)(iv)

No amendments have been filed subsequent to final rejection.

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SUMMARY OF CLAIMED SUBJECT MATTER

37 C.F.R. § 41.37(c)(1)(v)

None of the elements of the claims on appeal are construed by Appellant as means-for or steps-for elements under 35 U.S.C. § 112, ¶ 6.

Independent Claim 1

Independent claim 1 is directed to certain fluid handling devices, specifically, microfluidic substrate assemblies (e.g., the assembly of Fig. 1A; assembly of Figs. 6, 7A, 7B; system of Figs. 11A and 11B; system 400 of Fig. 13 and/or item 410 of system 400 of Fig. 13; manifold 456 of Figs. 14 and 15 and/or item 452 of manifold 456 of Figs. 14 and 15; system 500 of Fig. 16 and/or item 520 of system 500 of Fig. 16). Claim 1 defines the microfluidic substrate assembly as comprising a multi-layer laminated substrate (e.g., item 5 of Fig. 1A; item 70 of Fig. 1B; item 80 of Fig. 1C; item 40 of Figs. 7A and 8; item 130 of system of Fig. 11B; item 142 of Fig. 12; the multi-layer laminated substrate of item 410 of Fig. 13; the multi-layer laminated substrate of item 452 of Figs. 14 and 15; the multi-layer laminated substrate of item 520 of Fig. 16). The multi-layer laminated substrate defines at least one fluid inlet port (e.g., port 17 of Fig. 1A; port 17 of Figs. 6-8) and at least one microscale fluid flow channel (e.g., microchannels 13 and 15 of Fig. 1A, 5A-C, 6, 7A-B; microchannels 21-24 of Figs. 2A-D; microchannels 17 of Figs. 6-8) within the multi-layer substrate in fluid communication with the inlet port for transport of fluid. The microfluidic substrate assembly

further comprises at least one operative component (e.g., environmentally sensitive element 14 of Figs. 1 and 5A-C; external component-on-board 50 of Figs. 6 and 7A-B; removeable component 60 of Fig. 8) mounted aboard the multi-layer laminated substrate in communication with the microscale fluid flow channel.

Independent Claim 13

Independent claim 13 is directed to certain fluid handling devices, specifically, microfluidic substrate assemblies (e.g., the assembly of Fig. 1A; assembly of Figs. 6, 7A, 7B; system of Figs. 11A and 11B; system 400 of Fig. 13 and/or item 410 of system 400 of Fig. 13; manifold 456 of Figs. 14 and 15 and/or item 452 of manifold 456 of Figs. 14 and 15; system 500 of Fig. 16 and/or item 520 of system 500 of Fig. 16). Claim 13 defines the microfluidic substrate assembly as comprising a generally planar multi-layer laminated substrate (e.g., item 5 of Fig. 1A; item 70 of Fig. 1B; item 80 of Fig. 1C; item 40 of Figs. 7A and 8; item 130 of system of Fig. 11B; item 142 of Fig. 12; the multi-layer laminated substrate of item 410 of Fig. 13; the multi-layer laminated substrate of item 452 of Figs. 14 and 15; the multi-layer laminated substrate of item 520 of Fig. 16). The multi-layer laminated substrate defines at least one fluid inlet port (e.g., port 17 of Fig. 1A; port 17 of Figs. 6-8). The multi-layer laminated substrate also defines at least one microscale fluid flow channel (e.g., microchannels 13 and 15 of Fig. 1A, 5A-C, 6, 7A-B; microchannels 21-24 of Figs. 2A-D; microchannels 17 of Figs. 6-8) at each of more than one level within the multi-layer laminated substrate for transport of fluid. The multi-layer laminated substrate also defines at

least one microchannel via (e.g., microchannels 13 of Fig. 1A, 5A-C, 6, 7A-B; and through holes 124 of Fig. 10) extending between levels within the multi-layer laminated substrate for fluid communication between microscale fluid flow channels of different levels.

Independent Claim 15

Independent claim 15 is directed to certain microfluidic substrate assemblies (e.g., the assembly of Fig. 1A; assembly of Figs. 6, 7A, 7B; system of Figs. 11A and 11B; system 400 of Fig. 13 and/or item 410 of system 400 of Fig. 13; manifold 456 of Figs. 14 and 15 and/or item 452 of manifold 456 of Figs. 14 and 15; system 500 of Fig. 16 and/or item 520 of system 500 of Fig. 16). The microfluidic substrate assemblies of claim 15 comprise a multi-layer laminated substrate (e.g., item 5 of Fig. 1A; item 70 of Fig. 1B; item 80 of Fig. 1C; item 40 of Figs. 7A and 8; item 130 of system of Fig. 11B; item 142 of Fig. 12; the multi-layer laminated substrate of item 410 of Fig. 13; the multi-layer laminated substrate of item 452 of Figs. 14 and 15; the multi-layer laminated substrate of item 520 of Fig. 16) defining at least one fluid inlet port (e.g., e.g., port 17 of Fig. 1A; port 17 of Figs. 6-8) and at least one microscale fluid flow channel (e.g., microchannels 13 and 15 of Fig. 1A, 5A-C, 6, 7A-B; microchannels 21-24 of Figs. 2A-D; microchannels 17 of Figs. 6-8) in fluid communication with the inlet port for transport of fluid. In the microfluidic substrate assemblies of claim 15, at least one layer of the multi-layer laminated substrate is formed of plastic and the substrate assembly is operative and fluid tight at fluid pressure in the microscale fluid flow channel in excess of about 100 psi.

Independent Claim 20

Independent claim 20 is directed to certain microfluidic substrate assemblies (e.g., the assembly of Fig. 1A; assembly of Figs. 6, 7A, 7B; system of Figs. 11A and 11B; system 400 of Fig. 13 and/or item 410 of system 400 of Fig. 13; manifold 456 of Figs. 14 and 15 and/or item 452 of manifold 456 of Figs. 14 and 15; system 500 of Fig. 16 and/or item 520 of system 500 of Fig. 16). The microfluidic substrate assemblies of claim 20 comprise a multi-layer laminated substrate (e.g., item 5 of Fig. 1A; item 70 of Fig. 1B; item 80 of Fig. 1C; item 40 of Figs. 7A and 8; item 130 of system of Fig. 11B; item 142 of Fig. 12; the multi-layer laminated substrate of item 410 of Fig. 13; the multi-layer laminated substrate of item 452 of Figs. 14 and 15; the multi-layer laminated substrate of item 520 of Fig. 16) defining at least one fluid inlet port (e.g., e.g., port 17 of Fig. 1A; port 17 of Figs. 6-8) and at least one microscale fluid flow channel (e.g., microchannels 13 and 15 of Fig. 1A, 5A-C, 6, 7A-B; microchannels 21-24 of Figs. 2A-D; microchannels 17 of Figs. 6-8) within the multi-layer substrate and in fluid communication with the inlet port for transport of fluid. In the microfluidic substrate assemblies of claim 20, at least one layer of the multi-layer laminated substrate is formed of PEEK.

Independent Claim 27

Independent claim 27 is directed to certain microfluidic substrate assemblies (e.g., the assembly of Fig. 1A; assembly of Figs. 6, 7A, 7B; system of Figs. 11A and 11B; system 400 of Fig. 13 and/or item 410 of system 400 of Fig. 13; manifold 456 of Figs. 14 and 15 and/or

item 452 of manifold 456 of Figs. 14 and 15; system 500 of Fig. 16 and/or item 520 of system 500 of Fig. 16). The microfluidic substrate assemblies of claim 27 comprise a multi-layer laminated substrate (e.g., item 5 of Fig. 1A; item 70 of Fig. 1B; item 80 of Fig. 1C; item 40 of Figs. 7A and 8; item 130 of system of Fig. 11B; item 142 of Fig. 12; the multi-layer laminated substrate of item 410 of Fig. 13; the multi-layer laminated substrate of item 452 of Figs. 14 and 15; the multi-layer laminated substrate of item 520 of Fig. 16) defining at least one fluid inlet port (e.g., e.g., port 17 of Fig. 1A; port 17 of Figs. 6-8) and at least one microscale fluid flow channel (e.g., microchannels 13 and 15 of Fig. 1A, 5A-C, 6, 7A-B; microchannels 21-24 of Figs. 2A-D; microchannels 17 of Figs. 6-8) within the multi-layer substrate and in fluid communication with the inlet port for transport of fluid. In the microfluidic substrate assemblies of claim 27 at least first and second layers (e.g., layers 10 and 11 of Figs. 5A-C) of the multi-layer laminated substrate are selectively welded to each other to form a fluid-tight seal at least along a channel (e.g., channel 13 of Figs. 5A-C) within the multi-layer laminated substrate.

Independent Claim 31

Independent claim 31 is directed to certain methods of producing a multi-layer laminated substrate, specifically, methods comprising the steps of:

forming a surface-to-surface interface (e.g., as in Figs. 2A-D; Figs. 5A-C) by aligning a surface of a first substrate component against a surface of a second substrate component to form a substrate sub-assembly having an internal fluid channel at the

interface; and

exposing the sub-assembly to radiation to heat only one or more selected portions of the interface (e.g., as shown in Fig. 5C) to a temperature sufficient to weld the substrate components together, to form a fluid-tight seal between the substrate components at the interface along the fluid channel.

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GROUND OF REJECTION TO BE REVIEWED ON APPEAL

37 C.F.R. § 41.37(c)(1)(vi)

The grounds of rejection on appeal are the following:

Claims 1-6, 8-19 and 27-35 are rejected to under 35 U.S.C. 102(b) as being anticipated by WO 99/60397 or Wilding et al (US 5,928,880).¹

Claims 1-6 and 8-12 are rejected under 35 U.S.C. 102(e) as being anticipated by Dubrow et al. (US 6,475,364).

Claims 1-6 and 8-14 are rejected under 35 U.S.C. 102(b) as being anticipated by Wilding et al. (seemingly US 5,928,880).

Claim 7 is rejected under 35 U.S.C. 103(a) over WO 99/60397 or Wilding et al. or Dubrow et al. in view of Mastrangelo et al. (US 6,494,433).

Claims 20-26 are rejected under 35 U.S.C. 103(a) over WO 99/60397 or Wilding et al. or Dubrow et al.

¹ The citation of Wilding et al. in this first ground of rejection, as an alternative to WO 99/60397, is seen as redundant of the third ground of rejection which is based on seemingly the same Wilding et al. citation.

Claims 15-19 are rejected under 35 U.S.C. 103(a) over Wilding et al.

Claims 27-35 are rejected under 35 U.S.C. 103(a) over Wilding et al.

Appellant appeals the rejection of claims 1-35.

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ARGUMENT

37 C.F.R. § 41.37(c)(1)(vii)

I. Claims 1-6, 8-19 and 27-35 Are Patentable Over WO 99/60397

The citation WO 99/60397 fails to anticipate any of the subject claims.

Independent Claim 1 and Its Dependent Claims

In addition to other deficiencies, the '397 citation fails to anticipate claim 1 or claims dependent from claim 1 because it fails to disclose a microfluidic substrate assembly having at least 1 operative component on board a multi-layer laminated substrate, in fluid communication with a microscale fluid flow channel within the multi-layer substrate. Nor does the Examiner cite any specific disclosure in the '397 citation which could meet this requirement of claim 1 and its dependent claims. In this regard, for example, P11-P15 are shown merely schematically in FIG. 11 of the '397 citation. The corresponding discussion in the specification (page 14, line 24 to page 15, line 8) indicates that those valve and pump mechanisms engage interfaces on the cartridge rather than being mounted to the cartridge. For this reason alone, the rejection is without merit and should be overruled.

Other discussion in the '397 citation regarding valves, pumps etc. (e.g. at page 3, middle paragraphs) do not expressly teach that any such components are "mounted aboard the multi-

layer laminated substrate in communication with the microscale fluid flow channel” as called for in claim 1 of the present application. For this additional reason, the rejection is without merit and should be overruled.

Independent Claim 13 and Its Dependent Claims

With respect to claim 13 and claims dependent therefrom, the ‘397 citation fails as an anticipatory citation because it fails to disclose a microfluidic substrate assembly comprising a generally planar multi-layer laminated substrate defining at least one fluid inlet port and at least one microscale fluid flow channel at each of more than one level within the multi-layer laminated substrate for transport of fluid, and at least one microchannel via extending between levels within the multi-layer laminated substrate for fluid communication between microscale fluid flow channels of different levels. Accordingly, the rejection of claim 13 and claims dependent from claim 13 is in error and should be withdrawn.

While vias are mentioned in ‘397 (see, e.g., page 4, line 26) there is no express disclosure of vias extending between levels within a multi-layer laminated substrate for fluid communication between microscale fluid flow channel of different levels.

Independent Claim 27 and Its Dependent Claims

Regarding independent claim 27 and claims dependent from claim 27, the ‘397 citation fails as an anticipatory citation because it does not disclose a microfluidic assembly comprising a

multi-layer laminated substrate defining at least one fluid inlet port and at least one microscale fluid flow channel within the multi-layer substrate in fluid communication with the inlet port for transport of fluid, wherein at least first and second layers of the multi-layer laminated substrate are selectively welded to each other to form a fluid-tight seal at least along a channel within the multi-layer laminated substrate. Accordingly, the rejection of claim 27 and claims dependent from claim 27 is in error and should be overruled.

In particular, in addition to other shortcomings of the '397 citation, it fails to expressly teach a microfluidic substrate assembly wherein first and second layers of the multi-layer laminated substrate are selectively welded to each other to form a fluid-tight seal at least along a channel within the multi-layer laminated substrate. While the '397 citation discloses various alternative construction techniques (see e.g., page 18, bottom paragraph) no express disclosure is seen in the '397 citation of layers of a multi-layer laminated substrate being selectively welded to each other to form a fluid-tight seal at least along a channel within the multi-layer laminated substrate. Accordingly, the rejection is in error and should be overruled.

Independent Claim 31 and Its Dependent Claims

With respect to independent claim 31 and dependent claims 32-35, the '397 citation fails as an anticipatory citation because it fails to disclose a method of producing a multi-layer laminated substrate, comprising the steps of forming a surface-to-surface interface by

aligning a surface of a first substrate component against a surface of a second substrate component to form a substrate sub-assembly having an internal fluid channel at the interface; and exposing the sub-assembly to radiation to heat only one or more selected portions of the interface to a temperature sufficient to weld the substrate components together, to form a fluid-tight seal between the substrate components at the interface along the fluid channel. Accordingly, the rejection is in error and should be overruled.

In particular, in addition to other deficiencies, the '397 citation fails to teach a method of producing a multi-layer laminated substrate wherein only selected portions of a surface-to-surface interface are heated to a temperature sufficient to weld the substrate components together to form a fluid-tight seal between the substrate components at an interface along a fluid channel. Accordingly, the rejection should be overruled.

The rejection over Wilding et al. (US 5,928,880) is covered in the discussion below of the third ground of rejection.

II. Claims 1-6 and 8-12 Are Patentable Over Dubrow et al.

The citation Dubrow et al. (US 6,475,364) fails to anticipate any of the subject claims. Dubrow et al. is deficient and that it fails to disclose a microfluidic substrate assembly comprising a multi-layer laminated substrate defining at least one fluid inlet port and at least

one microscale fluid flow channel within the multi-layer substrate in fluid communication with the inlet port for transport of fluid; and at least one operative component mounted aboard the multi-layer laminated substrate in communication with the microscale fluid flow channel. Accordingly, the rejection of claim 1 and of claims dependent from claim 1 is in error and should be overruled.

In particular, in addition to other deficiencies, Dubrow et al. fails to disclose a microfluidic substrate assembly having at least one operative component mounted aboard a multi-layer laminated substrate in communication with a microscale fluid flow channel within the multi-layer substrate. The devices of Dubrow et al. are said to be used typically in conjunction with an overall analytical system (see, e.g., column 15, line 26 *et seq.*). There is no express disclosure in Dubrow et al. of operative components mounted aboard any such device. Accordingly, the rejection is in error and should be overruled.

III. Claims 1-6, 8-19 and 27-35 Are Patentable Over Wilding

The citation Wilding et al. (US 5,928,880) fails to anticipate any of the subject claims.

In addition to other deficiencies, Wilding fails to teach an operative component mounted aboard a multi-layer laminated substrate. The Examiner cites Fig. 6B of Wilding, but neither Fig. 6 nor any other disclosure in Wilding teaches an operative component mounted aboard a

multi-layer laminated substrate. Item 70 of Wilding's device is an "appliance," and is not multi-layer. Thus, item 10' of the Wilding device cannot meet present claim 1's requirement for an operative component because it is not mounted aboard a multi-layer laminated substrate.

Further, item 70 of Wilding's device is nowhere said to have a microscale channel. Thus, for this additional reason, item 10' of the Wilding device cannot meet present claim 1's requirement for an operative component mounted aboard a multi-layer laminated substrate.

Item 110' also cannot meet present claim 1's requirement for an operative component mounted aboard a multi-layer laminated substrate, because, as acknowledged by the Examiner, it is merely "stacked" on item 10'.

For all these reasons and any of them, the rejection over Wilding is in error and should be overruled.

Claim 4 is Further Patentable over Wilding

Claim 4 is patentable for the additional and independently sufficient reason, that Wilding fails to teach a microfluidic substrate assembly comprising an operative component mounted aboard the multi-layer laminated substrate, wherein the operative component is operative as a light sensor across a microscale fluid flow channel within the multi-layer substrate.

Claim 5 is Further Patentable over Wilding

Claim 5 is patentable for the additional and independently sufficient reason, that Wilding fails to teach a microfluidic substrate assembly comprising an operative component mounted aboard the multi-layer laminated substrate, wherein the operative component is operative as an ultrasonic actuator or transducer across a microscale fluid flow channel within the multi-layer substrate.

Claim 6 is Further Patentable over Wilding

Claim 6 is patentable for the additional and independently sufficient reason, that Wilding fails to teach a microfluidic substrate assembly comprising an operative component mounted aboard the multi-layer laminated substrate, wherein the operative component is operative to generate fluid pressure in a microchannel of the substrate.

Claim 8 is Further Patentable over Wilding

Claim 8 is patentable for the additional and independently sufficient reason, that Wilding fails to teach a microfluidic substrate assembly comprising an operative component mounted aboard the multi-layer laminated substrate, wherein the operative component mounted aboard the multi-layer laminated substrate is at least one electronic memory unit mounted to the substrate assembly and operatively connected to the microfluidic substrate assembly.

Claims 11 and 12 are Further Patentable over Wilding

Claims 11 and 12 are patentable for the additional and independently sufficient reason, that Wilding fails to teach a microfluidic substrate assembly comprising an operative component mounted aboard the multi-layer laminated substrate, wherein the operative component is operative to induce flow in a microchannel of the multi-layer laminated substrate endosmotically or by electrochemical evolution of gases.

Claims 15 and 16 are Further Patentable over Wilding

Claims 15 and 16 are patentable for the additional and independently sufficient reason, that Wilding fails to teach a microfluidic substrate assembly wherein at least one layer of the multi-layer laminated substrate is formed of plastic and the substrate assembly is operative and fluid tight at fluid pressure in the microscale fluid flow channel in excess of about 100 psi or 1000 psi, respectively.

Claims 19 and 27 are Further Patentable over Wilding

Claims 19 and 27 are patentable for the additional and independently sufficient reason, that Wilding fails to teach a microfluidic substrate assembly wherein the multiple plastic layers of the multi-layer laminated substrate are selectively welded one to another to form a fluid-tight seal along a channel within the substrate.

Claims 31-35 are Patentable over Wilding

Claims 31-35 are patentable over Wilding, because Wilding fails to teach a method of producing a multi-layer laminated substrate, comprising the steps of:

forming a surface-to-surface interface by aligning a surface of a first substrate component against a surface of a second substrate component to form a substrate sub-assembly having an internal fluid channel at the interface; and

exposing the sub-assembly to radiation to heat only one or more selected portions of the interface to a temperature sufficient to weld the substrate components together, to form a fluid-tight seal between the substrate components at the interface along the fluid channel.

Substantial discussion is presented in the present application regarding selective welding and its advantages in the context of the method defined by the subject claims. See, for example, page 10, line 15 to page 12, line 22, and page 26, line 15 to page 27, line 19. Wilding fails to teach selective welding in such context –or at all– and fails to provide any reason to go looking for those advantages. Accordingly, the rejection should be overruled.

IV. Claim 7 is Patentable Over WO 99/60397 or Wilding or Dubrow et al. in view of Mastrangelo et al.

Claim 7 is patentable over WO 99/60397 or Wilding et al. or Dubrow et al. in view of Mastrangelo, because Mastrangelo fails to cure the deficiencies of WO 99/60397, Wilding

or Dubrow et al. It is not asserted to cure such deficiencies and it does not. Accordingly, the rejection should be overruled.

V. Claims 20-26 are Patentable Over WO 99/60397 and Wilding et al. and Dubrow et al.

Claims 20-26 are rejected under 35 U.S.C. 103(a) over WO 99/60397 and Wilding et al. and Dubrow et al., because none of these citations teaches a microfluidic substrate assembly comprising a multi-layer laminated substrate defining at least one fluid inlet port and at least one microscale fluid flow channel within the multi-layer substrate in fluid communication with the inlet port for transport of fluid, in which at least one layer of the multi-layer laminated substrate is formed of PEEK.

The Examiner cites an aged decision to support the argument that it is *per se* obvious to select a known plastic on the basis of its suitability for an intended use. There is no such rule.

In the present case there is no basis cited for the implicit assertion that PEEK was known to be suitable for the multi-layer laminated substrates of the subject claims. Not is there any suggestion that PEEK solves a deficiency of the citations, nor even that it would be suitable for the devices of the citations. Accordingly, the rejection should be overruled.

VI. Claims 15-19 Are Patentable Over Wilding

Wilding fails to teach a microfluidic substrate assembly comprising a multi-layer laminated substrate defining at least one fluid inlet port and at least one microscale fluid flow channel in fluid communication with the inlet port for transport of fluid, wherein at least one layer of the multi-layer laminated substrate is formed of plastic and the substrate assembly is operative and fluid tight at fluid pressure in the microscale fluid flow channel in excess of about 100 psi.

In addition to other deficiencies, Wilding is silent as to the pressures at which its devices would be operative. Having in mind the mere stacking arrangement taught by Wilding, it is clear that high pressure operation is not contemplated and certainly is not taught. Accordingly, the rejection should be overruled.

Claim 16 is Further Patentable over Wilding

Claim 16 is patentable for the additional and independently sufficient reason, that Wilding fails to teach a microfluidic substrate assembly wherein at least one layer of the multi-layer laminated substrate is formed of plastic and the substrate assembly is operative and fluid tight at fluid pressure in the microscale fluid flow channel in excess of about 1000 psi. Nothing in Wilding suggests it should or could operate at this extreme pressure range.

Claim 19 is Further Patentable over Wilding

Claim 19 is patentable for the additional and independently sufficient reason, that Wilding fails to teach a microfluidic substrate assembly wherein the multiple plastic layers of the multi-layer laminated substrate are selectively welded one to another to form a fluid-tight seal along a channel within the substrate. The present application presents substantial discussion of this technique and of its advantages. See, for example, the sections cited above. Accordingly, the rejection should be overruled.

VII. Claims 27-35 are Patentable over Wilding**Independent Claim 27 and its Dependent Claims are Patentable**

In addition to other deficiencies, Wilding fails to teach a microfluidic substrate assembly comprising a multi-layer laminated substrate defining at least one fluid inlet port and at least one microscale fluid flow channel within the multi-layer substrate in fluid communication with the inlet port for transport of fluid, wherein at least first and second layers of the multi-layer laminated substrate are selectively welded to each other to form a fluid-tight seal at least along a channel within the multi-layer laminated substrate.

The Examiner acknowledges that Wilding is silent as to selective welding. While asserting that welding polymer layers is known, the Examiner fails to cite any basis to conclude that

selective welding in the context of the present invention as defined by the subject claims would have been obvious from Wilding. Accordingly, the rejection over Wilding is in error and should be overruled.

Independent Claim 31 and its Dependent Claims are Patentable

Here, again, Wilding fails to teach or suggest the claimed invention because it lacks fails to support the contention that selective welding would have been obvious in their context. Lacking such prima facie basis for concluding obviousness, the rejection is clearly in error and should be overruled.

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CONCLUSION

For all of the foregoing reasons, Appellant respectfully submits that the final rejection of claims 1-35 is improper and should be reversed.

Respectfully submitted,

Strand et al.

16 May 2005
Date



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CLAIMS APPENDIX

37 C.F.R. § 41.37(c)(1)(viii)

1. A microfluidic substrate assembly comprising:
a multi-layer laminated substrate defining at least one fluid inlet port and at least one microscale fluid flow channel within the multi-layer substrate in fluid communication with the inlet port for transport of fluid; and
at least one operative component mounted aboard the multi-layer laminated substrate in communication with the microscale fluid flow channel.
2. The microfluidic substrate assembly of claim 1 in which the operative component mounted aboard the multi-layer laminated substrate is in fluid communication with the at least one microscale fluid flow channel.
3. The microfluidic substrate assembly of claim 2 in which the operative component mounted aboard the multi-layer laminated substrate is operative as a fluid reservoir.
4. The microfluidic substrate assembly of claim 1 in which the operative component mounted aboard the multi-layer laminated substrate is operative as a light sensor across a microscale fluid flow channel within the multi-layer substrate.
5. The microfluidic substrate assembly of claim 1 in which the operative component mounted aboard the multi-layer laminated substrate is operative as an ultrasonic actuator or transducer across a microscale fluid flow channel within the multi-layer substrate.
6. The microfluidic substrate assembly of claim 1 in which the operative component mounted aboard the multi-layer laminated substrate is operative to generate fluid pressure in a microchannel of the substrate.

7. The microfluidic substrate assembly of claim 6 in which the operative component mounted aboard the multi-layer laminated substrate is a thermal actuator.
8. The microfluidic substrate assembly of claim 6 in which the operative component is a micromachined pump, diaphragm pump, syringe pump or volume occlusion pump.
9. The microfluidic substrate assembly of claim 1 in which the operative component mounted aboard the multi-layer laminated substrate is operative to induce flow in a microchannel of the multi-layer laminated substrate endosmotically or by electrochemical evolution of gases.
10. The microfluidic substrate assembly of claim 1 in which the multi-layer laminated substrate further comprises at least one fluid outlet port in fluid communication with the fluid inlet port within the multi-layer substrate.
11. The microfluidic substrate assembly of claim 1 in which the operative component mounted aboard the multi-layer laminated substrate is at least one electronic memory unit mounted to the substrate assembly and operatively connected to the microfluidic substrate assembly.
12. The microfluidic substrate assembly of claim 11 further comprising at least one operative component mounted aboard the multi-layer laminated substrate in communication with the microscale fluid flow channel and operative to generate an electronic signal corresponding to a detected characteristic of fluid in the microscale fluid flow channel, wherein the at least one electronic memory unit is connected to the operative component to receive and record the electronic signal.

13. A microfluidic substrate assembly comprising a generally planar multi-layer laminated substrate defining

at least one fluid inlet port and at least one microscale fluid flow channel at each of more than one level within the multi-layer laminated substrate for transport of fluid, and

at least one microchannel via extending between levels within the multi-layer laminated substrate for fluid communication between microscale fluid flow channels of different levels.

14. The microfluidic substrate assembly of claim 13 in which the at least one microchannel has a configuration which is straight, curvo-linear, serpentine or spiral.

15. A microfluidic substrate assembly comprising a multi-layer laminated substrate defining at least one fluid inlet port and at least one microscale fluid flow channel in fluid communication with the inlet port for transport of fluid, wherein at least one layer of the multi-layer laminated substrate is formed of plastic and the substrate assembly is operative and fluid tight at fluid pressure in the microscale fluid flow channel in excess of about 100 psi.

16. The microfluidic substrate assembly of claim 15 in which the multi-layer laminated substrate is operative and fluid tight at fluid pressure in the microscale fluid flow channel in excess of about 1000 psi.

17. The microfluidic substrate assembly of claim 15 in which the multi-layer laminated substrate further comprises rigid plates sandwiching the plastic layer between them.

18. The microfluidic substrate assembly of claim 17 in which multiple layers of the multi-layer laminated substrate are formed of plastic and are welded one to another, the rigid plates sandwiching the multiple plastic layer between them.
19. The microfluidic substrate assembly of claim 18 in which the multiple plastic layers of the multi-layer laminated substrate are selectively welded one to another to form a fluid-tight seal along a channel within the substrate.
20. A microfluidic substrate assembly comprising a multi-layer laminated substrate defining at least one fluid inlet port and at least one microscale fluid flow channel within the multi-layer substrate in fluid communication with the inlet port for transport of fluid, in which at least one layer of the multi-layer laminated substrate is formed of PEEK.
21. The microfluidic substrate assembly of claim 20 in which the at least one PEEK layer is formed of amorphous PEEK.
22. The microfluidic substrate assembly of claim 20 in which the at least one PEEK layer is formed of crystalline PEEK.
23. The microfluidic substrate assembly of claim 20 in which the at least one PEEK layer comprises IR absorbing species in concentration sufficient for IR welding of the PEEK layer.
24. The microfluidic substrate assembly of claim 23 in which the IR absorbing species is distributed substantially homogeneously throughout the PEEK layer.

25. The microfluidic substrate assembly of claim 23 in which the IR absorbing species is disposed on the surface of the PEEK layer.
26. The microfluidic substrate assembly of claim 25 in which the IR absorbing species is selected from dyes, zinc oxide, silicon oxide and metal species.
27. A microfluidic substrate assembly comprising a multi-layer laminated substrate defining at least one fluid inlet port and at least one microscale fluid flow channel within the multi-layer substrate in fluid communication with the inlet port for transport of fluid, wherein at least first and second layers of the multi-layer laminated substrate are selectively welded to each other to form a fluid-tight seal at least along a channel within the multi-layer laminated substrate.
28. The microfluidic substrate assembly of claim 27 in which the multi-layer laminated substrate further comprises at least one environmentally sensitive structure intolerant to a transition glass temperature of the first and second layers.
29. The microfluidic substrate assembly of claim 28 in which the environmentally sensitive structure is an architectural feature of the microscale fluid flow channel, a mechanical sensor, a mechanical device, an electrical sensor, an electrical device, a fluid, chromatography reagents and any combination of them.
30. The microfluidic substrate assembly of claim 28 in which the environmentally sensitive structure is disposed in the microscale fluid flow channel.
31. A method of producing a multi-layer laminated substrate, comprising the steps of: forming a surface-to-surface interface by aligning a surface of a first substrate component against a surface of a second substrate component to form a substrate sub-assembly

having an internal fluid channel at the interface; and
exposing the sub-assembly to radiation to heat only one or more selected portions of the interface to a temperature sufficient to weld the substrate components together, to form a fluid-tight seal between the substrate components at the interface along the fluid channel.

32. The method of claim 31 further comprising the steps of coating at least a selected area of the surface of the first substrate component with a radiation absorptive material prior to forming the surface-to-surface interface.

33. The method of claim 32 in which the absorptive material is coated onto only one or more selected portions of the surface of the first substrate component and the sub-assembly is exposed non-selectively to IR radiation.

34. The method of claim 32 in which the absorptive material is coated onto the entire surface of the first substrate component and only one or more selected portions of the interface are exposed to IR radiation.

35. The method of claim 34 in which the sub-assembly is exposed to radiation through a mask having a configuration corresponding to the one or more selected portions of the interface.

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EVIDENCE APPENDIX

37 C.F.R. § 41.37(c)(1)(ix)

NONE

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RELATED PROCEEDINGS APPENDIX

37 C.F.R. § 41.37(c)(1)(x)

This Appendix contains copies of decisions rendered by a court or the Board in any proceeding identified pursuant to 37 C.F.R. § 41.37(c)(1)(ii) – Related Appeals and Interferences.

NONE

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